

Claims

1. A coated pellet comprising
 - a) a pellet core which comprises venlafaxine hydrochloride;
 - 5 b) a first coating which comprises a lipophilic layer or a sparingly water-soluble layer, and
 - c) a second coating which comprises a water-insoluble polymer or polymer mixture.
2. A pellet as claimed in claim 1 wherein the core additionally comprises a carrier, e.g. microcrystalline cellulose.
- 10 3. A pellet as claimed in claim 1 or claim 2 wherein the core further comprises a binder.
4. A pellet as claimed in claim 3 wherein the binder comprises a cellulose derivative.
- 15 5. A pellet as claimed in claim 3 or claim 4 wherein the binder comprises hydroxypropyl methylcellulose (HPMC).
6. A pellet as claimed in claim 1 or claim 2 wherein the lipophilic layer comprises a fat, fatty alcohol or wax.
- 20 7. A pellet as claimed in any preceding claim wherein the lipophilic layer comprises cetostearyl alcohol, castor oil or dibutyl phthalate.
8. A pellet as claimed in claim 1 or claim 2 wherein the sparingly water-soluble layer
25 comprises a sugar, e.g. lactose, in the form of an aqueous suspension wherein the concentration of the sugar is at least 0.3 g/ml.
9. A pellet as claimed in any preceding claim wherein the water-insoluble polymer is
30 selected from polymethacrylate dispersions, ethylcellulose dispersions and polyvinyl acetate dispersions.

10. A composition comprising pellets as claimed in any preceding claim.
11. A composition as claimed in claim 10 in tablet, hard gelatine capsule or sachet form.
- 5 12. A process for preparing coated pellet cores which process comprises the steps of
- i) forming a pellet core mixture comprising venlafaxine hydrochloride with water or an aqueous solution of a binder,
 - 10 ii) extruding and spheronising the mixture, drying and sieving,
 - iii) applying a first coating, and
 - iv) applying a second coating,
- 15 wherein the process is carried out in the absence or substantial absence of any organic solvent medium at least in the second coating.
13. A process as claimed in claim 12 wherein the pellet core mixture further comprises
- 20 microcrystalline cellulose and HPMC.
14. A process as claimed in claim 12 or claim 13 wherein the process is carried out in the absence or substantial absence of any organic solvent medium in both the first and second
- 25 coatings.
15. A coated pellet produced by the process as claimed in any one of claims 12 to 14.
16. A coated pellet consisting of or consisting essentially of
- a) a core containing venlafaxine hydrochloride in an amount of between 30 and 60 % by
 - 30 weight, microcrystalline cellulose in an amount of between 40 and 65% by weight, and

- 12 -

HPMC K 4 M in an amount of between 0.3 and 0.8% by weight, wherein the respective weights are in relation to the double-coated core;

b) a first coating containing cetostearyl alcohol in an amount of between 1.7 and 3.5 % by weight of the first-coated pellet core; and

c) a second coating containing an acrylate-based polymer in an amount of between 9 and 13% by weight based on the total weight of the double-coated core, and talc in an amount of between 3 and 8% by weight based on the total weight of the double-coated pellet core.

17. A composition comprising pellets as claimed in claim 16.